

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P O Box 1450 Alexandria, Virgiria 22313-1450 www.uspio.gov

ELECTRONIC

11/09/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,824	02/27/2001	David J Squirrell	63775US008	3738
32692 7590 11/09/2009 3M INNOVATIVE PROPERTIES COMPANY PO BOX 33427 ST. PAUL, MN 55133-3427			EXAMINER	
			STEADMAN, DAVID J	
			ART UNIT	PAPER NUMBER
			1656	
			NOTIFICATION DATE	DELIVERY MODE

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

LegalUSDocketing@mmm.com LegalDocketing@mmm.com

Application No. Applicant(s) 09/763 824 SQUIRRELL ET AL. Office Action Summary Examiner Art Unit David J. Steadman 1656 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 24 December 2008 and 01 July 2009. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) See Continuation Sheet is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) See Continuation Sheet is/are allowed. 6) Claim(s) 106-109.112-120 and 163-175 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner, Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) □ Some * c) □ None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date. Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application

Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/30/08.

6) Other:

Continuation of Disposition of Claims: Claims pending in the application are 106-109,112-120,125,126,129,130,133,134,137,138,141,142,145,146,149,150,153,154,157,158 and 161-175.

Continuation of Disposition of Claims: Claims allowed are

125,126,129,130,133,134,137,138,141,142,145,146,149,150,153,154,157,158,161 and 162.

Art Unit: 1656

DETAILED ACTION

Status of the Application

[1] Claims 106-109, 112-120, 125-126, 129-130, 133-134, 137-138, 141-142, 145-146, 149-150, 153-154, 157-158, and 161-175 are pending in the application.

- [2] Applicant's amendment to the claims, filled on 7/1/09, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.
- [3] Receipt of a sequence listing in computer readable form (CRF), a paper copy thereof, a statement of their sameness, a statement that no new matter has been added to the specification by the paper copy of the sequence CRF, and an amendment directing entry of the substitute sequence listing paper copy into the specification, all filed on 3/20/09, is acknowledged.
- [4] Receipt of an information disclosure statement, filed on 12/30/08, is acknowledged.
- [5] Applicant's remarks filed on 12/24/08 in response to the Office action mailed on 6/24/08 have been fully considered and are deemed to be persuasive to overcome at least one of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Rejections and/or objections directed to claims 110-111, 121-124, 127-128, 131-132, 135-136, 139-140, 143-144, 147-148, 151-152, 155-156, and 159-160 are withdrawn solely in view of the instant claim amendment to cancel these claims.
- [6] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Art Unit: 1656

Fxaminer's Amendment

[7] In order to expedite prosecution of the application, the examiner initiated a telephonic interview with Ms. Charlene Yager on 11/2/09. A proposed examiner's amendment was presented to Ms. Yager and because of Office-imposed deadlines, the examiner requested a decision by 11/4/09. The examiner noted that if a decision was not received by this date, a final Office action would be forthcoming. As of the drafting of this Office action, no reply has been received. Adopting the proposed claim amendment in response to this Office action would obviate the rejection under 35 U.S.C. 112, second paragraph, raised in this Office action.

Information Disclosure Statement

- [8] The information disclosure statement (IDS) submitted on 12/30/08 was filed after the mailing date of the non-final Office action on 6/24/08. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.
- [9] Foreign patent document reference EP 0680515 B1 is lined through as the examiner can find no copy of this reference in the application file.

Specification/Informalities

[10] The objection to the specification under 35 U.S.C. 132(a) as introducing new matter into the disclosure by listing "Xaa" in SEQ ID NO:39 of the sequence listing as Application/Control Number: 09/763,824

Art Unit: 1656

being "Asp" is <u>withdrawn</u> in view of the substitute sequence listing filed on 3/20/09, which identifies Xaa as Cys, Ala, or Asn, which is supported in the original specification at p. 7, lines 26-36.

Claim Rejections - 35 USC § 112, Second Paragraph

[11] Claims 106-109, 112-120, and 163-175 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is necessitated by amendment.

Claims 106 (claims 107-109 and 112-120 dependent therefrom) and 163 (claims 164-175 dependent therefrom) are indefinite for reasons that follow.

Claim 110 as filed on 4/28/08 was a dependent claim that further limited the recombinant polypeptide of claim 106. According to applicant's instant remarks, claim 106 has been amended to *incorporate* the limitations of claim 110 and to write claims 110 and 111 in independent form (see, e.g., instant remarks at p. 10, top and p. 11, middle). However, based on applicant's amendment to claim 106 and newly added claim 163, the claims read as a *fusion protein*, *i.e.*, a fusion of a variant of SEQ ID NO:38 and 41 as set forth in claim 106 and a fusion of a variant of SEQ ID NO:38 and 42 as set forth in claim 163. However, based on the specification and prosecution history, it appears that applicant does not intend for the claimed recombinant protein to be limited to a fusion protein. It is suggested that applicant clarify the meaning of the claims.

Art Unit: 1656

Double Patenting Rejection(s)

[12] The provisional obviousness-type double patenting rejection of claims 106-107, 109, 112-115, and 118-120 as being unpatentable over claims 1-4, 6-10, 14-16, 18-19, 21, and 35-37 of co-pending Application No. 10/111,723 is withdrawn in view of the instant claim amendment to claim 106. While the claims of the '723 application support a 214C/354K/357F variant of *P. pyralis* luciferase, the combination of references does not teach or suggest a variant *P. pyralis* luciferase having mutations at positions 214, 232, and 354 as encompassed by the claims.

Claim Rejections - 35 USC § 103

- [13] The rejection of claims 106-108, 112-115, and 118-120 under 35 U.S.C. 103(a) as being unpatentable over Thompson et al. (*J. Biol. Chem.* 272:18766-18771, 1997; "Thompson U") in view of Thompson et al. (*Gene* 103:171-177, 1991; "Thompson V"), Hirokawa et al. (US Patent 6,074,859; "Hirokawa") and Lowe et al. (US Patent 6,132,983; "Lowe") is <u>withdrawn</u> in view of the instant claim amendment to claim 106. The combination of references does not teach or suggest a variant *P. pyralis* luciferase having mutations at positions 214, 232, and 354 as encompassed by the claims.
- [14] The rejection of claim 109 under 35 U.S.C. 103(a) as being unpatentable over Thompson U in view of Thompson V, Hirokawa, and Lowe as applied to claims 106-108. 112-115. 118-120 above, and further in view of additional teachings of Thompson

Application/Control Number: 09/763,824

Art Unit: 1656

U and Lowe is <u>withdrawn</u> in view of the instant claim amendment to claim 106. The combination of references does not teach or suggest a variant *P. pyralis* luciferase having mutations at positions 214, 232, and 354 as encompassed by the claims.

[15] The rejection of claims 116-117 under 35 U.S.C. 103(a) as being unpatentable over Thompson U in view of Thompson V, Hirokawa, and Lowe as applied to claims 106-108, 112-115, and 118-120 above and further in view of Barnes (*PNAS* 87:9183-9187, 1990) is <u>withdrawn</u> in view of the instant claim amendment to claim 106. The combination of references does not teach or suggest a variant *P. pyralis* luciferase having mutations at positions 214, 232, and 354 as encompassed by the claims.

Conclusion

[16] Status of the claims:

Claims 106-109, 112-120, 125-126, 129-130, 133-134, 137-138, 141-142, 145-146, 149-150, 153-154, 157-158, and 161-175 are pending.

Claims 106-109, 112-120, and 163-175 are rejected.

Claims 125-126, 129-130, 133-134, 137-138, 141-142, 145-146, 149-150, 153-

154, 157-158, and 161-162 would appear to be in condition for allowance.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filled within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

Art Unit: 1656

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Steadman/ Primary Examiner, Art Unit 1656